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Display Date 7-29-99
Publication Date 7-30-99
Certifier MMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2335]

Medical Gloves; Draft Guidance Manual; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Medical Glove Guidance Manual.'' The draft guidance represents a major revision of this guidance document, which was initially issued in 1993 under the title ''Guidance for Medical Gloves: A Workshop Manual.'' This draft guidance is intended to provide current information to assist manufacturers and others in obtaining marketing clearance, applying manufacturing and design controls, and properly labeling medical gloves. This draft guidance also includes recommendations for limits on the amounts of glove powder and natural latex protein present on surgeon's and patient examination gloves. Elsewhere in this issue of the **Federal Register**, the FDA is proposing reclassification of surgeon's gloves and patient examination gloves into class II (special controls) because the agency believes that special controls are necessary to provide reasonable assurance of the safety and effectiveness of the gloves. The agency is proposing that the draft guidance ''Medical Glove Guidance Manual'' be one of the special controls, and the agency is requesting comment on the content of the manual at this time.

DATES: Submit written comments concerning this draft guidance by (*insert date 90 days after date of publication in the* **Federal Register**) for consideration prior to implementation of the guidance as a special control.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance. Submit written requests for single copies on a 3.5'' diskette of the guidance

document entitled ''Medical Glove Guidance Manual'' to the Division of Small Manufacturers Assistance'' (HFZ–220), Center for Devices and Radiological, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Arthur K. Yellin, Center for Devices and Radiological Health (HFZ–200), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 800–638–2041, ext. 146, 301–443–6597, ext. 146.

SUPPLEMENTARY INFORMATION:

I. Background

Medical gloves are a significant factor in the protection of both patients and health care personnel in the United States. Because of the increased reliance on medical gloves as a barrier against transmission of infectious diseases and contaminants, it is imperative that they be manufactured and labeled in accordance with FDA laws and regulations.

Originally entitled ''Guidance for Medical Gloves: A Workshop Manual,'' this document was first published in May 1993 to assist manufacturers in preparing premarket notification (510(k)) submissions for medical gloves and applying quality systems requirements (formerly known as good manufacturing practices, or GMP) to the production of medical gloves. It has been used extensively as a text in training workshops provided by the FDA to the regulated industry. It is heavily relied upon and widely recognized as a valuable resource to those currently in, or seeking to enter, the United States medical glove market.

The draft guidance has been revised to address and emphasize the agency's growing concerns about the role of glove powder as a cause of foreign body reactions and as a carrier of airborne natural latex allergens. The draft guidance recommends that manufacturers of powdered surgeon's

and patient examination gloves limit the amount of powder to no more than 120 milligrams (mg) of powder per glove, regardless of glove size. It further recommends that manufacturers of powder-free surgeon's and patient examination gloves limit the amount of total trace (residual) powder on gloves to no more than 2 mg particulate weight (based on the American Society for Testing Materials Standard Test Method for Residual Powder on Medical Gloves (D 6124-97)) per glove, regardless of glove size.

The draft guidance also includes a recommendation that manufacturers of natural rubber latex surgeon's and patient examination gloves limit the amount of water-extractable protein on the gloves to no more than 1200 micrograms of protein per glove, regardless of glove size.

II. Significance of Guidance

This draft guidance represents the agency's current thinking on medical gloves. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

Persons interested in obtaining a copy of the medical glove guidance manual may do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes the medical glove guidance manual, device safety alerts, access to **Federal Register** reprints, information on premarket submissions including lists of approved applications and manufacturers' addresses, small

manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. The medical glove guidance manual is available at''http://www.fda.gov/cdrh/manual/glovmanl.pdf''.

You may also receive instructions about obtaining the medical glove guidance manual via your fax machine. To do so call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt, press 1 to access DSMA Facts, at the second voice prompt, press 2, and then enter the document number (852) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

IV. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the* **Federal Register**) submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found

in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/15/99
July 15, 1999

Margaret M. Dotzel
Acting Associate Commissioner for
Policy

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

BILLING CODE 4160–01–F